

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

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This Document Relates To:  
*All Cases*

**PLAINTIFFS' MEMORANDUM  
IN SUPPORT OF MOTION TO  
EXCLUDE THE TESTIMONY OF  
ANTONIA HUGHES, RN, PHD  
UNDER FED. R. EVID. 702-703**

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**I. INTRODUCTION**

The Court should exclude Antonia Hughes from serving as an expert witness because her report and testimony are nothing more dubious lay testimony packaged as an expert opinion. Defendant cannot meet its burden of establishing that Nurse Hughes' testimony—which can be summarized as “operating rooms are not sterile”—is based on a reliable methodology under Rule 702 and *Daubert*. Nurse Hughes has done nothing more than (a) describe an operating room and her experience with surgical procedures, (b) report on having read articles outside of her knowledge and credentials, and (c) offered subjective opinions, of questionable materiality, on matters outside of her knowledge and expertise. Her testimony is neither reliable nor helpful to the jury and should be excluded.

## II. FACTUAL BACKGROUND

On June 1, 2017, Defendants disclosed the expert report of Antonia Hughes, RN, BSN, MA, CNOR. Ex. A<sup>1</sup>, Hughes Rpt. Ms. Hughes is a Certified Registered Nurse. She has a bachelor's and master's degree in nursing and a certification as an operating room nurse. Ex. A, Hughes Rpt. at 1; Ex.B, Hughes Dep. at 7:3-9:22. She has conducted no research on and admits that she is not an expert in: operating room design, airflow or air handling in the operating room, orthopedics, anesthesiology, hospital ventilation, aerobiology, microbiology, FDA clearance, or infectious disease. Ex. B, Hughes Dep. at 28:11-30:5, 32:14-22, 79:24-80:1. She has never designed a medical device. *Id.* at 29:20-21. Nurse Hughes has no knowledge of the mechanisms of causing an infection with respect to a periprosthetic joint infection. *Id.* at 73:10-13. Nurse Hughes failed to conduct any research about the safety of the Bair Hugger. *Id.* at 83:5-8, 85:4-6, 120:3-21, 167:19-23.

Nurse Hughes' expert opinion is about the "flow" of the patient in the operating room. *Id.* at 85:4-6. She opined that the operating room environment and equipment are clean, but not completely sterile, and that actions taken reduce, but do not eliminate, bacteria. Ex. A, Hughes Rpt. at 6; Ex. B, Hughes Dep. at 115:12-116:21, 123:19-124:24. Her report and deposition testimony, however, merely recite her observations of procedures that take place in the operating room, without offering any scientific data or articles about the presence or cause of bacteria and without conducting any testing. *See*

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<sup>1</sup> All references to Ex. \_\_ are references to exhibits to the Declaration of Genevieve M. Zimmerman in Support of Plaintiffs' Motion to Exclude the Opinions and Testimony of Antonia Hughes, filed concurrently herewith.

*generally*, Ex. A, Hughes Rpt. at 2-6; Ex. B, Hughes Dep. at 123:4-124:24, 132:1-134:6. Nurse Hughes has no scientific basis for her opinions. *Id.* at 134:3-6, 171:1-6.

Nurse Hughes' lack of any specialized knowledge relevant to the case is demonstrated by the fact that she wrote in her report and testified about the need to minimize traffic in the operating room during total hip and total knee replacement surgeries. However, when asked why this was necessary, Nurse Hughes did not know why reducing traffic was necessary, but simply relied on articles that say doing so improves patient outcomes. *Id.* at 20:1-20, 25:17-22, 28:7-25, 31:9-14.

Instead of offering any true expert opinion relevant to the case, Nurse Hughes offered subjective, irrelevant, and potentially misleading opinions that lack any academic or scientific rigor. For instance, Nurse Hughes' report states that in an operating room, "downward air flow is strong," yet she fails to quantify "strong," provide any basis for the opinion, or explain its relevance. Ex. A, Hughes Rpt. at 2. Later she provides the opinion that the airflow through a Bair Hugger blanket is "a gentle or mild air flow," *id.* at 4, yet again fails to quantify either term, provide any basis for the opinion, or explain its relevance. At deposition, Hughes defended her opinion that the surgical room airflow is "strong" because she could "feel it on the back of [her] neck. *Id.* at 68:4-6, 94:7-95:2.

And, even though Hughes admits she is not qualified to testify about the engineering aspect of air flow in the operating room, she doesn't hesitate to offer testimony about other devices in the operating room that purportedly blow air as part of the "patient flow" process. *Id.* at 145:4-148:25. In fact, Hughes provides supportive citations in only five places in her report; otherwise, her report is replete with conclusory

statements with absolutely no scientific, academic, or other support. *See, generally*, Ex. A, Hughes Rpt.; Ex. B, Hughes Dep. at 108:19-24.

### III. LEGAL STANDARDS

Federal Rule of Evidence 702 permits expert witnesses to testify if the subject of their testimony is relevant, the witnesses are qualified to express their opinions, and the proposed evidence upon which they base their testimony is reliable or trustworthy. *Polski v. Quigley Corp.*, 538 F.3d 836, 839 (8<sup>th</sup> Cir. 2008).

Courts are the gatekeeper of evidence proffered under Rule 702, “to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

Expert testimony must be trustworthy for it to be reliable. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993). That is, the testimony must be supported by appropriate validation. *Id.* Four nonexclusive factors control the reliability of expert testimony: “(1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique’s known or potential rate of error; and (4) the level of the theory or technique’s acceptance within the relevant discipline.” *Id.* at 593-94.

The Eighth Circuit considers additional factors as well, including: “whether the expertise was developed for litigation or naturally flowed from the expert’s research; whether the proposed expert ruled out other alternative explanations; and whether the

proposed expert sufficiently connected the proposed testimony with the facts of the case. *Polski*, 538 F.3d at 839. The party seeking admission of expert testimony has the burden of demonstrating its reliability. *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007).

A “very significant” criterion for reliability is whether the expert’s testimony is based on research independent of litigation. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9<sup>th</sup> Cir. 1995) (*Daubert II*). “If the proffered expert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence and explain precisely how they went about reaching their conclusions and point to some objective source—a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like—to show that they have followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in their field.” *Id.*, 43 F.3d at 1317-19.

Where the factual basis, data, or the methodology employed by the expert are sufficiently called into question, the court must determine not only if the testimony is reliable, but also whether it has a valid connection to the pertinent inquiry. *Kumho Tire Co.*, 526 U.S. 137 at 149. Expert testimony must therefore “logically advance[] a material aspect of the proposing party’s case.” *Daubert*, 509 U.S. at 597. The court should not admit opinion evidence “that is connected to existing data only by the *ipse dixit* of the expert,” *Gen. Elec. Co. v. Joiner*, 522 U.S. at 157, or that is based on his own unique methodology rather than a respected methodology. *Groobert v. President and Directors of Georgetown College*, 219 F. Supp. 2d 1, (D.D.C. 2002). Under these circumstances, a

court may conclude there is simply too great an analytical gap between the data and the opinion.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

#### IV. ARGUMENT

##### **A. Nurse Hughes Must Be Excluded as an Expert Witness Because Her Report and Expert Testimony Do Not Assist with Deciding the Case.**

Nurse Hughes’ expert testimony is that the operating room is not completely sterile. However, there is no dispute in the case that the operating room is not a completely sterile environment. “In order to be admissible, expert testimony must be both relevant to a material issue and reliable.” *Margolies v. McCleary, Inc.*, 447 F.3d 1115, 1120 (8th Cir. 2006). Under Fed. R. Evid. 401, evidence must be relevant and consequential, and under Fed. R. Evid. 702, opinions must be “based upon sufficient facts or data,” and the expert must have “applied the principles and methods reliably to the facts of the case.” The **conclusion** of Hughes’ report consists of four sentences that restate the same empty observation:

In conclusion, it is my expert opinion that the operating room is a clean, but not completely sterile, environment. Bacteria cannot be completely eliminated from the operating room environment. The operating room equipment that will be close to the surgical field (and not covered by sterile drapes) contain bacteria and are not sterile. It is my expert opinion that many actions taken to reduce bacteria, e.g. patient’s skin prep, wiping down equipment in the operating room, will not eliminate and kill all bacteria.

Ex. A, Hughes Rpt. at 6.

In addition to offering no scientific explanation, factual basis, data, or methodology to reach this “conclusion” (which is not a disputed fact), Hughes makes no effort to articulate why it is material to any issue in the case. Hughes Rpt. at 2-6.; Hughes

Dep. at 123:4-124:24, 132:1-134:6. Thus, Nurse Hughes’ testimony must be excluded because it is neither relevant to a material issue nor reliable. Instead, Defendants are apparently attempting to use Hughes as a vehicle to plant the *ideas* of its liability defense—the safety of the Bair Hugger, air flow, the presence of other equipment in the operating room that blow air, etc.—through an “expert” who neither has the qualifications to discuss those subject matters nor has engaged in any reliable methodology that others can scrutinize.

**B. Nurse Hughes Must Be Excluded as an Expert Witness Because She Is Not Actually Offering Expert Testimony.**

Nurse Hughes is not offering testimony based on any specialized knowledge, training or expertise. “Expert testimony that merely repeats information capable of easy comprehension by a jury is excludable. For it to be admissible, it must go ‘beyond the ken of people of ordinary intelligence’” *Khoday v. Symantec Corp.*, 93 F. Supp.3d 1067, 1084 (D. Minn. 2015) (citing *U.S. v. Davis*, 457 F.2d 817, 824 (8<sup>th</sup> Cir. 2006)); *see e.g. Am. Family Mut. Ins. Co. v. Kline*, 780 F.Supp.2d 839, 841–43 (S.D.Iowa 2011) (excluding expert testimony describing a 911 phone call where the call recording was available to show the jury). Even if the single conclusion offered by Hughes—that one cannot kill all bacteria in an operating room—was relevant, and even if she was competent to submit it, the jury does not need this testimony from Hughes to decide the case. *See Lee v. Andersen*, 616 F.3d 803, 808–09 (8th Cir.2010) (finding that an expert’s testimony was not appropriate where it merely described, without any specialized

knowledge, images that “the jury was entirely capable of analyzing” on their own). For this additional reason, her testimony must be excluded.

**C. Nurse Hughes’ Should Be Excluded from Testifying as An Expert Because She Is a Biased Advocate.**

Both Nurse Hughes and her attorney confirmed at her deposition that she was not opining about the safety and efficacy of the Bair Hugger. Hughes Dep. at 167:25-169:15. Nonetheless, her report concludes as fact—without any scientific support--that “forced air warming devices [are] safe for use in the operating room and that there is no correlation between use of such devices and post-operative infection.” Hughes Rpt., p. 4. Nurse Hughes is admittedly neither qualified nor designated to offer an opinion on these critical issues and her inclusion of these opinions is improper advocacy.

“An expert does not advocate during litigation but acts as a source of information and opinion.” *Deadwood Canyon Ranch, LLP v. Fidelity Exploration & Production Company*, 2013 WL 11971254, at \*3 (D.N.D., 2013). “When expert witnesses become partisans, objectivity is sacrificed to the need to win.” *Cacciola v. Selco Balers, Inc.*, 127 F.Supp.2d 175, 184 (E.D.N.Y. 2001). Here, Nurse Hughes acted outside of the constraints of Rule 709 in order to advocate for Defendants. *See In re Trasyolol Products Liability Litigation*, 709 F.Supp.2d 1323, 1351 (S.D.Fla. 2010) (excluding an expert who became “an advocate, presented with the trappings of an expert but with no expectation or intention of abiding by the opinion constraints of Rule 702.”). Thus, for this additional reason, her testimony should be excluded.



**D. Nurse Hughes Must Not Be Permitted to Testify about the Safety and Efficacy of the Bair Hugger Device.**

Even though she was not retained to opine about the safety and efficacy of the Bair Hugger, she concluded in her report and testified at her deposition that forced-air warming devices are medically-necessary and safe. Ex. A, Hughes Rpt., p. 4; Ex. B, Hughes Dep., at 46:18-22, 71:10-72:9, 97:8-98:14. Nurse Hughes, however, is not qualified to render a medical opinion or testify about the safety and efficacy of the Bair Hugger. As a nurse in the operating room, Nurse Hughes admitted that she does not have the education, knowledge, training, or expertise to make these conclusions. Ex.B, Hughes Dep at 28:11-30:5, 29:20-21, 32:14-22, 73:10-13, 79:24-80:1, 83:5-8, 85:4-6, 86:1-88:25 120:3-21, 167:19-23. In addition, she does not have the experience to offer this testimony because she does not use the Bair Hugger in the operating room and does not monitor the temperature of the patient during surgery. Ex. B, Hughes Dep.at 71:10-72:9.

Thus, based on her admission and lack of qualifications, Nurse Hughes must be excluded from offering testimony about whether use of the Bair Hugger is medically-necessary, safe or effective. *Elswick v. Pikeville United Meth. Hosp. of Ky, Inc.*, 50 Fed. Appx.193, 195 (6<sup>th</sup> Cir. 2002) (excluding nurse from providing expert medical opinion outside of her expertise).

**V. CONCLUSION**

For the reasons stated above, Plaintiffs ask the Court to Exclude the Testimony of Antonia Hughes, RN, BSN, MA, CNOR.

Dated: September 12, 2017.

Respectfully submitted,

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